ORIGINAL ARTICLE

Management of Type 2 Diabetes Mellitus: Is it in Accordance with the Guidelines?

G C Chan, MMed (Fam Med)*, O Ghazali, MPH, E M Khoo, MRCGP, AM*****

*Family Medicine Specialist, Poliklinik Komuniti Peringgit, Jalan Pantai Peringgit, 75400 Melaka, **Deputy Director of Health, State Health Office, Melaka, ***Associate Professor, Department of Primary Care Medicine, University of Malaya, 50603 Kuala Lumpur

Summary

A cross-sectional study was conducted among 517 patients with diabetes mellitus at all health centres in Melaka Tengah District to examine whether these patients and their associated cardiovascular risk factors were managed according to current guidelines. All patients had Type 2 diabetes mellitus with mean age of 57.9 ± 10.5 years and the mean duration of diabetes was 7.2 ± 6.0 years. The glycaemic control was poor with 53.6% of the patients having HbA1c above 8% (mean=8.5%) and 24% of them had microalbuminuria. Among these patients with poor glycaemic control, about 47.6% of them were on monotherapy. Three hundred and fifty (67.7%) patients had hypertension but only 11 (3.1%) achieved target blood pressure of less than 130/80 mmHg. Only 18.3% of the diabetics with hypertension were prescribed angiotensin converting enzyme inhibitors and 0.3% with angiotensin receptor blockers. Nearly two-third of them had low-density lipoprotein cholesterol greater than 2.6 mmol/l (mean=3.4 mmol/l) but only 6.8% were prescribed lipid-lowering agents. Aspirin was prescribed to 8.2% of diabetics aged above 40 years. Sixteen percent of the patients smoked, 53% did not do any exercise, and the mean BMI was 26.8 kg/m^2. The management of diabetes mellitus and its associated cardiovascular risk factors was sub-optimal on the basis of current clinical guidelines. A greater effort in educating doctors in the health centres about these management and adherence to the guidelines is important in reducing patients' risk of cardiovascular disease and its associated morbidity and mortality.

Key Words: Type 2 diabetes mellitus, Primary care, Cardiovascular risk factors

Introduction

The prevalence of diabetes mellitus in adult is increasing worldwide; from 4.0% (135 million) in 1995, it is estimated to rise to 5.4% (300 million) by the year 2025 and the main area of this increase will occur in developing countries[1]. In Malaysia, the National Health and Morbidity Survey II (NHMS II) conducted in 1996 revealed that 8.3% of the population had diabetes mellitus[2]. This figure was alarming when compared to the estimated worldwide prevalence.

Recently, the Diabcare Asia Study[3] that involved six Asian countries showed that only about 18% of diabetic patients had good glycaemic control based on fasting glucose or glycosylated haemoglobin (HbA1c) level and 54% had a total cholesterol level of > 5.2 mmol/l. In a local study, only 9% of the diabetic patients achieved good glycaemic control and 65% had undesirable weight gain while on treatment[4].

Type 2 diabetes mellitus is an independent risk factor for macrovascular disease, and its common coexisting conditions such as hypertension, obesity and dyslipidaemia are modifiable risk factors for cardiovascular diseases[5]. The cardiovascular mortality for a diabetic patient without a previous myocardial

This article was accepted: 28 June 2005

Corresponding Author: Chan Giin Cherng, Klinik Cheng No 20, Jalan CB-1, Taman Cheng Baru, 75250 Melaka

infarction was the same as that for a non-diabetic patient with myocardial infarction[6].

National practice guidelines on management of diabetes mellitus[7] and hypertension[8] were available in all health centres in Melaka Tengah District to help primary care doctors to better manage their patients with diabetes mellitus. The adherence and implementation of the guidelines is important to improve disease outcome and prevention of cardiovascular diseases among diabetic patients. Hence, the purpose of this study was to examine whether the management of diabetes mellitus and its associated cardiovascular risk factors among diabetic patients at health centres conforms to current guidelines.

Materials and Methods

This was a cross sectional study conducted in Melaka Tengah District, one of the three districts in Melaka state, from August to October 2003. All 11 government health centres providing primary healthcare in the district were included in this study. There are one or two primary healthcare doctors working in each health centre and all of them have basic medical degrees.

A systematic sampling (1:5) was used for registered diabetic patients who came for follow up during this period of study. The inclusion criteria are Malaysian citizens and the patients had been followed up for diabetes mellitus in the health centre for at least 12 months. Patients who had newly diagnosed diabetes mellitus, had defaulted treatment for more than six months, were critically ill or had mental health or difficulty in communication were excluded.

After the doctor had interviewed and examined the selected patient, trained medical assistants of the respective health centres gathered data from the patient's medical record into a specially designed form. Data collected included demographic characteristics, duration of diabetes mellitus, current smoking habit, self reported exercise, latest blood pressure (BP) measurement, body mass index (BMI), fasting lipid profile (FLP), glycosylated haemoglobin levels (HbA1c), results of microalbuminuria, types of antidiabetic and antihypertensive drugs prescribed.

Patients with Type 2 diabetic mellitus in this study were defined according to the criteria set by the Malaysian practice guidelines for Type 2 diabetes mellitus[7] or if the patients were known to have diabetes mellitus as evidenced from referral letters to the health centres by general practitioners or hospital specialists.

Hypertension was taken as a systolic BP of 140mm Hg or greater and/or a diastolic BP of 90 mmHg or greater or patients with known hypertension currently on antihypertensive medication[8]. Standard mercury sphygmomanometer with appropriately sized cuff was used to measure patient's BP by a doctor using the right arm of the patient who had been rested for at least 5 minutes and seated with the arm supported at heart level. An average of two BP readings taken 2 minutes apart was used and the reading was rounded to the nearest 2 mmHg. All the primary care doctors were briefed about the methodology prior to the commencement of the study.

BMI was calculated from patient's height and weight using standard measurement equipments in the health centres. Blood and urine samples were collected during the study period for assessment of FLP, HbA1c, and microalbuminuria. Fasting lipid profile (total cholesterol, low-density lipoprotein cholesterol [LDL-C], high-density lipoprotein cholesterol [HDL-C], triglycerides) was assessed using Hitachi Chemistry Analyzer 902 whereas HbA1c was assessed quantitatively using DCA 2000 Analyzer based on latex immunoagglutination inhibition. The HbA1c has been recommended to be maintained below 7% and HbA1c level of more than 8% indicates poor control[5]. Microalbuminuria was semiquantitatively detected by using CLINITEK® microalbumin reagent strips and CLINITEK® 50 urine analyzer. Patient would be considered to have microalbuminuria if they have 2 separate positive results taken two weeks apart after excluding other causes such as urinary tract infection. Albumin is normally present in the urine at a concentration of less than 30 mg albumin/g creatinine (3.4 mg albumin/mmol creatinine). Microalbuminuria is indicated at a ratio result of 30 – 300 mg/g (3.4 – 33.9 mg/mmol) and clinical albuminuria (macroalbuminuria) at a ratio result of > 300 mg/g (> 33.9 mg/mmol).

SPSS version 11 was used for data analysis. The associations between ethnicity and mean HbA1c, LDL-C and BMI were analyzed with One-way Analysis of Variance (ANOVA). The associations between ethnicity and the presence of microalbuminuria, current smoker status were analyzed using Chi-squared test. P value of less than 0.05 was chosen for interpretation of statistical significance.

Results

A total of 517 patients with diabetes mellitus were recruited. All of them had type 2 diabetes mellitus with four of them on adjunctive insulin regime. Three hundred and thirteen (60.5%) patients were female. The mean age of the patients was 57.9 ± 10.5 years (range 24 to 91 years). The mean duration of diabetes mellitus was 7.2 years ± 6.0 years (range 1 to 31 years).

There were 285 (55.1%) Malay, 190 (36.8%) Chinese and 41 (7.9%) Indian in this study. This distribution of ethnic groups was fairly representative of the total 5,256 registered diabetic patients in Melaka Tengah District in year 2003 where there were 53.6% Malay, 36.0% Chinese and 9.0% Indian[9].

The glycaemic control of the patients was poor. The mean HbA1c level was 8.5% (SD = 1.8%, range 4.6% to 13.3%). Two hundred and seventy seven (53.6%) patients had HbA1c > 8%, 151 patients (29.2%) had HbA1c between 7 – 8% and 89 (17.2%) had HbA1c <7%. Indians had the highest mean HbA1c followed by Malay and Chinese but there was no significant difference shown. (see Table I)

Of the patients with HbA1c > 8%, about 47.6% of them were prescribed monotherapy (68.3% with glibenclamide and 27.3% with metformin). Approximately 69% of the poorly controlled group had BMI of 30 kg/m² and above but they were prescribed glibenclamide only. The most common oral hypoglycaemic agent used was glibenclamide (76.8%) followed by metformin (61.5%), gliclazide (6.0%), acarbose (2.7%) and chlorpropamide (1.5%).

About a quarter of the patients were found to have microalbuminuria, being highest in the Chinese followed by Malay and Indian but there was no significant association shown. (see Table I)

In this study, 350 (67.7%) patients had hypertension (≥140/90 mmHg). Based on the national clinical practice guidelines on the management of hypertension[8], only 11(3.1%) of them had achieved target blood pressure of < 130/80 mmHg. For those who did not achieve target BP, 134 (39.5%) of them were not on any anti-hypertensive drugs and the average number of antihypertensive medications used in this group of patients was 1.4 (Figure 1). Sixty four (18.3%) diabetic hypertensive, regardless of albuminuria status, were prescribed ACE inhibitors (captopril and enalapril) and 0.3% was given ARBs (losartan).

The mean low-density lipoprotein cholesterol (LDL-C) of patients with diabetes mellitus was 3.4 ± 1.1mmol/l (range 0.8 to 8.4 mmol/l). The LDL-C levels were not significantly different among the different ethnic groups. (see Table I) Three hundred and twenty five patients (62.9%) had LDL-C level greater than 2.6 mmol/l but only 35 (6.8%) of them were prescribed lipid-lowering agents. The agents used were lovastatin (81.8%) and gemfibrozil (18.2%).

Anti-platelet agent such as aspirin was prescribed in only 40 (8.2%) patients with age above 40 years (n=490). In those with concomitant hypertension (n=350), only 19 (5.4%) were prescribed aspirin.

Eighty (16%) patients were current smokers and 89% of them were males. No significant difference was found between ethnic groups and smoking habit. (see Table I) The mean duration of smoking was 24.1 ± 13.7 years, (range 1 to 60 years) with an average of 16 ± 12 cigarettes, (range 2 to 80 cigarettes) smoked per day.

About 274 (53%) patients did not do any exercise. Taking a walk was the most common form of reported exercise (33.9%) among those who did. The average number of exercise per week was 4.6 ± 2.1, (range 1 to 7) with a mean duration of 33.9 minutes for each occasion (SD=20.6 minutes, range 5 to 120 minutes).

The mean BMI was 26.8 ± 4.7 kg/m², (range 14.7 to 44.9 kg/m²) with nearly two-thirds of them overweight or obese. (see Figure 2) The BMI is significantly higher in the Malays followed by the Indians and the Chinese. ($p < 0.0001$, see Table I)

Discussion

Over half of the diabetic patients at the health centres in Melaka Tengah District had poor glycaemic control (HbA1c > 8). This could be attributed to improper use of oral hypoglycaemic agents by the doctors as nearly half of the diabetics were on monotherapy. Combination therapy may be needed in these patients to achieve target glycaemic goal[7]. In addition, metformin should be the agent of choice in obese diabetic patients as glibenclamide increases appetite and leads to weight gain[7]. However, instead of metformin, nearly three quarter of the poorly controlled group of patients with BMI 30 kg/m² and above in this study were prescribed glibenclamide alone.

Table I: Summary of CVD risk factors in different ethnic groups

	Malay	Chinese	Indian	All patients	P value
Mean HbA1c (%)	8.6	8.3	8.7	8.5	0.1
Mean LDL-C (mmol/l)	3.402	3.404	3.287	3.400	0.9
Microalbuminuria (%)	21.7	24.7	19.5	24.0	0.9
Current smoker (%)	16.1	15.3	12.2	16.0	0.9
Mean BMI (kg/m^2)	27.6	27.2	25.6	26.8	P<0.0001

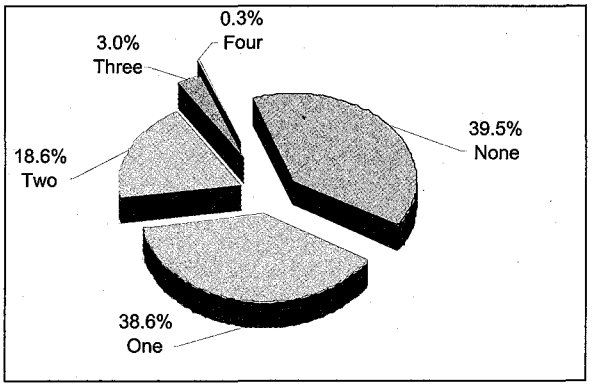

Fig. 1: Number of antihypertensive agents prescribed in diabetic with hypertension (n=350)

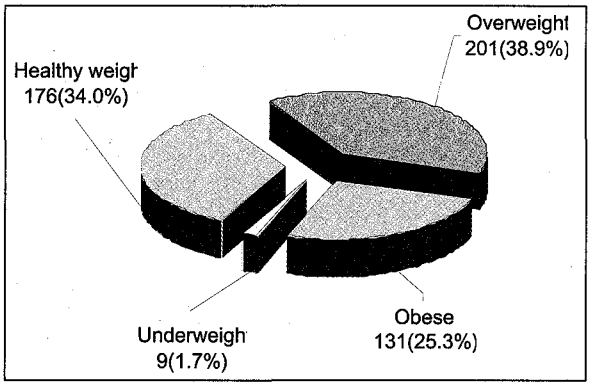

Fig. 2: BMI among patients with diabetes mellitus (n=517)

Although the association between ethnic groups and HbA1c and microalbuminuria was not significantly different, Indians appeared to have the highest HbA1c but the lowest prevalence of microalbuminuria whereas Chinese had the highest prevalence of microalbuminuria but lowest in the level of HbA1c. These findings were similarly observed in a study conducted in Singapore recently[10]. The reasons need exploration in future. More aggressive glycaemic control is needed especially among the Indians for prevention of future cardiovascular diseases (CVD). In addition, early detection of microalbuminuria is also important, as it is an independent predictor of progressive renal disease,[11] as well as a well-established marker of increased CVD risk in type 2 diabetes mellitus[12].

The prevalence of hypertension among patients with diabetes mellitus in this study was 67.7% and this result was comparable with studies elsewhere (20 to 60%)[13]. People with coexisting diabetes mellitus and hypertension have approximately twice the risk of getting cardiovascular diseases [13] and control of blood pressure is effective in reducing cardiovascular events and mortality[14]. In this study, majority of the patients did not achieve the target blood pressure of less than 130/80 mmHg. This poor control of hypertension could be due to several factors: the doctors were not aggressive enough in their management of hypertension. The average number of antihypertensive drugs used was only 1.4 while clinical trials had demonstrated that more than 65% of the people with diabetes and hypertension would require two or more antihypertensive medications to achieve the target blood pressure of 130/80 mmHg[15]. In addition, the use of ACE inhibitors and ARBs were low among the diabetics with hypertension. Both ACE inhibitors and ARBs have been shown to reduce the incidence of cardiovascular diseases and stroke in patients with diabetes mellitus as well as affecting the progression of diabetic nephropathy and reduce albuminuria. ARBs have been shown to reduce the progression to macroalbuminuria as well[16,17]. Although the availability of these medications especially ARBs may be an issue in the health centres, greater awareness of the benefits of these medications and optimal control of BP in diabetic patients need to be addressed.

With regard to lipid and anti-platelet therapies, stratification of risk factors for coronary heart disease (CHD) in type 2 diabetes mellitus shows that LDL-C is the best predictor of CHD[18] and lowering of LDL-C to ≤

2.6 mmol/l has been recommended as the primary goal of therapy for adult[19]. On the other hand, aspirin has been recommended for primary[20] and secondary prevention[21] of cardiovascular events in diabetics and non-diabetic individuals. Despite this, very few diabetics with LDL-C greater than 2.6 mmol/l and who are above 40 years old[8] in this study were prescribed lipid-lowering agents and aspirin.

We find a lower prevalence of current smoker among patients with diabetes mellitus than that was found in the NHMS II[2] (16% vs 24.8%). This is encouraging as smoking significantly enhances the risk of cardiovascular diseases, contributing to premature morbidity and mortality in patients with diabetes mellitus[22]. Studies had shown that the prevalence of smoking may be equivalent among individuals with or without diabetes mellitus and only half of them were advised to quit smoking by their health care providers[23]. Therefore it is important to assess the smoking status for all diabetics as part of routine care and quit smoking counselling and pharmacological help should be provided.

Regular exercise improves blood glucose control, reduce cardiovascular risk factors, contribute to weight loss, and improve individual well-being[24-26]. A lack of exercise was documented in over half of the patients with diabetes mellitus in this study. A regular physical activity program, adjusted to the presence of complications should be encouraged in all patients with diabetes.

Obesity is a common coexisting problem in patients with diabetes mellitus. It is estimated to occur in about 60% of type 2 diabetics in western countries[27-28]. We found 38.9% and about a quarter of the diabetics were overweight and obese and these figure were much higher than that among the general population of Malaysia in 1996 in the NHMS 2 where 16.6% were found to be overweight and 4.4% obese[2]. Excess weight is associated with an increased incidence of cardiovascular diseases, type 2 diabetes mellitus, hypertension, stroke, dyslipidaemia, osteoarthritis and certain cancers[29]. Therefore, obese patients with diabetes mellitus especially the Malays who had the highest BMI should be reinforced on diet and weight control besides good glycaemic control.

This study shows that vast majority of the patients with diabetes mellitus had poor glycaemic control and their blood pressure did not achieve target goals. In addition, the under use of medications especially ACEIs and ARBs, coupled with patients' unhealthy lifestyles and behaviours, placing them at high risk of cardiovascular diseases. This sub-optimal management could be related to the factors of patients, healthcare providers, policies and the availability of certain medications. Patient factors include difficulties in adherence to prescribed regimens, inaccessibility to medical care, financial barriers, lack of understanding about the seriousness of uncontrolled diabetes mellitus and fear of hypoglycemia[30]. For healthcare providers, the main factor may be due to the nonadherence to clinical recommendations among the primary healthcare doctors. In addition, the non-availability of certain antidiabetic and antihypertensive medications in the health centres may restrict their choice of pharmacological treatment in managing patients with diabetes mellitus.

This study is limited by its cross sectional design. However, it does provide some useful information about the doctors' management of diabetes mellitus and its concomitant cardiovascular risk factors in the health centres. Primary care doctors should be encouraged to adopt and promote practice guidelines in their everyday practice and these guidelines should be made readily accessible at the point of service. Continuing medical education can be provided to improve doctors' knowledge and attitudes on diabetic care. Regular audits of medical records and clinical management of primary care doctors by senior doctors or Family Medicine Specialists are other strategies to ensure the adherence of guidelines and achievement of optimal management in patients with diabetes mellitus.

Conclusion

The management of diabetes mellitus and its concomitant cardiovascular risk factors in Melaka Tengah District health centres was sub-optimal to those recommended by the current guidelines. Greater efforts in disseminating information and guidelines and continuing medical education will help to decrease the morbidity and mortality of patients with diabetes mellitus.

Acknowledgements

The authors wish to thank the primary care doctors in Melaka Tengah District for participating in this study, and also to the Director of Health, Melaka, for permission to conduct this study.

* This paper was presented (poster presentation) at the 5th MOH-AMM Scientific Meeting 2004 in Sunway, Selangor.

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